



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

g3505d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

WARNING LETTER

NWE-31-02W

VIA FEDERAL EXPRESS

August 28, 2002

Frank L. Pericolosi, President
Valley Fish Company, Inc.
144 Hartford Avenue
East Granby, Connecticut 06026

Dear Mr. Pericolosi:

We inspected your firm, located at 144 Hartford Avenue in East Granby, Connecticut, on July 17 and 18, 2002, and found that you have serious deviations from the Seafood HACCP regulations, Title 21, Code of Federal Regulations, (21 C.F.R.) Part 123. These deviations cause the tuna, mahi mahi, vacuum packaged raw fish, and pasteurized canned crabmeat processed by your firm to be adulterated within the meaning of section 402(a)(4) (21 U.S.C. § 342(a)(4)) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations are as follows:

You must have written HACCP plans to control any food safety hazards that are reasonably likely to occur, to comply with 21 C.F.R. § 123.6(b). However, your firm does not have HACCP plans for:

- a) Scombrotoxin species to control the food safety hazard of histamines;
- b) Vacuum packaged raw fish to control the food safety hazard of *Clostridium botulinum*; and
- c) Pasteurized canned crabmeat to control the food safety hazard of pathogens.

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We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should outline the specific steps you are taking to correct these deviations. You may wish to include in your response documentation, such as a completed HACCP plan, or other useful information that would assist in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 C.F.R. § 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Bruce R. Ota, Compliance Officer, One Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issues in this letter, please contact Mr. Ota at (781) 596-7762.

Sincerely,

A handwritten signature in black ink, appearing to read 'Gail T. Costello', with a stylized flourish extending to the right.

Gail T. Costello
District Director
New England District